Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the therapeutic effects of posterior tibial nerve stimulation and the anticholinergic drug sulifenacin in patients with hyperactive bladder

Protocol summary

Study aim
Comparison of the therapeutic effects of posterior tibial nerve stimulation and the anticholinergic drug sulifenacin in patients with hyperactive bladder

Design
A clinical trial with a control group, with a parallel group; A single-blind, randomized, phase III study on 118 patients. A block method was used for randomization.

Settings and conduct
This study is conducted in Ghaem Mashhad Hospital, Razavi Khorasan Province. 118 patients with symptoms of urinary urgency, urinary incontinence, nocturnal enuresis and frequency of urination referred to Qaim Hospital (Aj) in 1402 were randomly divided into two intervention or control groups (A-B). At the beginning and end of the study, the average quality of life score and overactive bladder symptoms are evaluated.In this study, the outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria
The study population consisted of 118 patients with complaints of urinary urgency, urinary incontinence, nocturnal enuresis and frequent urination, who referred to Ghaem Hospital in 1402. Inclusion criteria: having informed consent to enter the study, urinating more than 8 times in 24 hours, at least 6 months had passed since the onset of symptoms. Exclusion criteria: refusal to continue the plan, pregnancy, history of surgery to treat urinary incontinence, treatment with anticholinergic drugs.

Intervention groups
The study groups are divided into two groups, intervention group (A): for 12 weeks, 2 sessions every week and each session for 30 minutes under the treatment of posterior tibial nerve stimulation or control (B): patients treated with the anticholinergic drug visol solifenacin with The dose is 5 mg once a day for 12 weeks.

Main outcome variables
Mean quality of life score and frequency distribution of overactive bladder symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190618043934N25**
Registration date: **2024-05-13, 1403/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-13, 1403/02/24**
Update count: **0**

Registration date
2024-05-13, 1403/02/24

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-20, 1403/02/01
Expected recruitment end date
2024-06-21, 1403/04/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the therapeutic effects of posterior tibial nerve stimulation and the anticholinergic drug sulifenacin in patients with hyperactive bladder

Public title
Posterior tibial nerve stimulation and anticholinergic drug solifenacin in patients with overactive bladder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to enter the study Passing urine more than 8 times in 24 hours At least 6 months have passed since the onset of symptoms Creating an emergency to urinate, which is accompanied by urgency urinary incontinence
Exclusion criteria:
Refusal to continue the plan pregnancy having a history of surgery to treat urinary incontinence treatment with anticholinergic drugs having a urinary tract infection
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **118**
Randomization (investigator's opinion)
Randomized
Randomization description
Placement of patients in two intervention and control groups by simple random block method into two groups where each person in one of the intervention group (A): treated with stimulation of the posterior tibial nerve or control and group (B): patients treated with anti-inflammatory drugs Cholinergic visol solifenacin will be placed. First, blocks of four were created as AABB, ABAB, BABA, BBAA, ABBA, BAAB. Blocks are placed in sealed envelopes. Then one of these envelopes is randomly removed for the first patient and the placement of the next 3 patients in each of the following groups is determined. Then randomization is done for other patients as well.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome evaluator: The study manager (4th year urology assistant) will evaluate and analyze the data without knowing the placement of the patients in the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Vakil Abad Boulevard, Mashhad, Khorasan Razavi, Iran
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Province
Razavi Khorasan
Postal code
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Approval date
2023-05-09, 1402/02/19
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.128

Health conditions studied

1

Description of health condition studied
Overactive bladder
ICD-10 code
N32.81
ICD-10 code description
Overactive bladder

Primary outcomes

1

Description
Quality of Life
Timepoint
At the beginning of the study and 3 months after the start of the intervention
Method of measurement
Using a questionnaire to assess the quality of life of patients with lower urinary tract disorders

2

Description
Overactive bladder symptoms
Timepoint
At the beginning of the study and 3 months after the start of the intervention

Method of measurement
Using the overactive bladder symptoms evaluation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group: for 12 weeks, 2 sessions per week and each session for 30 minutes under posterior tibial nerve stimulation treatment and before and after the intervention (3 months after the start of the intervention) the considered parameters are evaluated.
Category
Treatment - Other

2

Description
Control group: Group second intervention: The patients are treated with the anticholinergic drug Visol solifenacin manufactured by Abidi company with a dose of 5 mg once a day for 12 weeks. Before and after the intervention (3 months after the intervention), the considered parameters are evaluated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Quaem Mashhad University
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available